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|-------------------------------|------------------------|---------------------|--|
| Notice of Allowability | Application No. | Applicant(s) | |
| | 09/621,781 | FISHER ET AL. | |
| | Examiner | Art Unit | |
| | David A. Lambertson | 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendments filed December 23, 2002 and April 15, 2003.
2. ☒ The allowed claim(s) is/are 1,7-14 and 38-40.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☒ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☒ CORRECTED DRAWINGS must be submitted.
 - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☒ hereto or 2) ☒ to Paper No. 13.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>1103.</u> |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____ | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Lisa B. Kole, M.D., Ph.D. on November 5, 2003.

Miscellaneous

It is noted that Applicant has traversed the objection to the drawings presented in the first paragraph. Applicant is dutifully reminded that there were additional objections presented in a Draftsperson's review (form PTO-948), and these objections have not been resolved. Applicant is urged to resolve these issues in response to this Notice. A courtesy copy of the aforementioned form PTO-948 is attached to this Office Action to expedite the process.

It is additionally noted that the Bibliographic data has been updated to properly reflect Applicant's amended claim to priority, as well as the current status of US Application No. 09/052,753 as US Application No. 6,472,320. This is additionally reflected in Applicant's amendment to the priority claim in the first line of the specification.

Oath/Declaration

The Oath/Declaration provided in response to the priority claim amendment is objected to as being unexecuted in accordance with either 37 CFR 1.66 or 1.68. Specifically, the required

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signatures of the inventors are absent from the newly filed Declaration. Applicant is now required to submit a substitute declaration or oath to correct the deficiencies set forth above. The substitute oath or declaration must be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability" (PTO-37). Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136. Failure to timely file the substitute declaration (or oath) will result in **ABANDONMENT** of the application. The transmittal letter accompanying the declaration (or oath) should indicate the date of the "Notice of Allowance" (PTOL-85) and the application number in the upper right hand corner.

The application has been amended as follows:

Please amend the claims as follows:

1. An isolated nucleic acid comprising a PEG-3 promoter having promoter activity comprising the nucleotide sequence beginning with the guanosine (G) at position 1507 and ending with the cytosine (C) at position 1970 of SEQ ID NO: 1.

7. The nucleic acid of claim 1, wherein the nucleic[.]acid is operably linked to a gene of interest.

11. A vector comprising the nucleic acid of any one of claims [1 and 7 to 10] 1, 7, 8, 9 or 10.

38. An isolated nucleic acid comprising a [PEG-3] promoter comprising:

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(i) a PEA3 protein binding sequence consisting of the nucleotide sequence beginning with the thymidine (T) at position 1672 and ending with the thymidine (T) at position 1677 of SEQ ID NO: 1,

(ii) a TATA sequence consisting of the nucleotide sequence beginning with the thymidine (T) at position 1748 and ending with the adenosine (A) at position 1753 of SEQ ID NO: 1, and

(iii) an AP1 protein binding sequence consisting of the nucleotide sequence beginning with the thymidine (T) at position 1781 and ending with the adenosine (A) at position 1787 of SEQ ID NO: 1,

wherein said [PEG-3] promoter is at least about 464 nucleotides long and has [PEG-3] promoter activity.

39. An isolated nucleic acid comprising a [PEG-3] promoter comprising:

(i) a PEA3 protein binding sequence consisting of the nucleotide sequence beginning with the thymidine (T) at position 1672 and ending with the thymidine (T) at position 1677 of SEQ ID NO: 1,

(ii) a TATA sequence consisting of the nucleotide sequence beginning with the thymidine (T) at position 1748 and ending with the adenosine (A) at position 1753 of SEQ ID NO: 1, and

(iii) an AP1 protein binding sequence consisting of the nucleotide sequence beginning with the thymidine (T) at position 1781 and ending with the adenosine (A) at position 1787 of SEQ ID NO: 1,

wherein said nucleic acid has promoter activity.

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40. The isolated nucleic acid of claim 39, wherein the entire length of the [PEG-3] promoter is at least about 99% identical to the sequence of nucleotides 1507 to 1970 of SEQ ID NO: 1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson, Ph.D.
AU1636



JAMES KETTER
PRIMARY EXAMINER